

REMARKS

STATUS OF CLAIMS

Paragraph 15 on page 6 of paper no. 10 indicates the presence of allowable subject matter and mentions SEQ ID NOS: 2 and 3. As these two sequences are recited in claims 57 and 69, applicants believe that these two claims are allowable over the prior art of record. Confirmation of this interpretation is requested.

OBVIOUSNESS-TYPE DOUBLE PATENTING

All pending claims are rejected as obvious over claims 1-25 of U.S. Patent No. 6,190,856. The patented claims are said to "encompass" the application claims.

The patented claims matured from originally filed claims 31-37. These claims were elected and claims 1-30 and 38-44 were not elected pursuant to the restriction requirement in Paper No. 4 dated March 6, 1998. (Copy attached.) Claims 31-37 were cancelled in the subject application in Amendment A. (See paragraph 3, page 2, paper no. 10.)

The two sets of claims were held to be separate inventions in the '856 patent prosecution. Applicants relied on the restriction requirement in filing the subject divisional application. Section 121 of Title 35 of the United States Code states that "[a] patent issuing on an application with respect to which a requirement for restriction under this section has been made...shall not be used as a reference ...against a divisional application. ..." Because the subject application is a proper divisional application of the reference patent, the rejection is improper and should be withdrawn.

REJECTION OF CLAIMS 1, 5, 9, 45-51, 53, 55-56 UNDER 35 U.S.C. §102(b)

Shatz (U.S. 5,270,120) is cited as anticipating claims 1, 5, 9, 45-51, 53, 55-56.

In order to find anticipation, each and every element set forth in the claim must be found in a single prior art reference. *Verdegal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q. 2d 1051, 1053 (Fed. Cir. 1987). Shatz does not teach each element and thus fails to anticipate the claims.

The rejected claims recite:

- a homogeneous population of detectable virus expressing a ligand on its surface;
- contacting a sample with the detectable virus;
- detecting binding of the virus to the sample.

Shatz does not employ a homogeneous population of virus expressing a ligand on its surface. Shatz employs a library of mixed identities. Shatz' invention does not employ a detectable virus expressing a ligand on its surface. Shatz' invention employs plasmids which express fusion products. The fusions are of a DNA binding protein and a library of peptides. Col. 2, lines 33-39. The cells encoding the fusion proteins are lysed. Col. 2, lines 51-53. The lysis is performed under conditions such that the fusion protein remains bound to the vector that encodes it. Shatz does not teach a virus with a ligand expressed on its surface.

Shatz also does not teach the steps of contacting a virus with a sample and detecting the presence of a polypeptide in the sample by virus binding to the sample. Shatz screens a library of heterogeneous peptides by binding them to a receptor and isolating the peptide from the library that binds to the receptor.

Thus, Shatz uses a receptor to isolate a peptide ligand from a heterogeneous library of peptides. The present invention detects a polypeptide in a sample by binding the polypeptide to a homogeneous population of a detectable virus.

Claims 5 and 9 further specify that the ligand on the surface of the virus

- was previously demonstrated to specifically bind the selected polypeptide; or
- was previously demonstrated to specifically bind the selected cellular protein.

Neither of these limitations are met by Shatz. Shatz screens from a library and selects and identifies a binding partner. Shatz does not teach using previously recognized specific binding partners. Shatz teaches a screening method to identify a peptide ligand in a library. The present claims use a ligand to detect the presence of its polypeptide binding partner in a sample.

Shatz fails to teach all elements of the claims. Therefore, Shatz does not anticipate the rejected claims.

REJECTION OF CLAIMS 1, 5, 9, 17, 22, 45-51, 53, 55-56, 58-63, 65, 67-68 UNDER 35 U.S.C. §103(a)

The enumerated claims are rejected as unpatentable over a combination of Shatz (U.S. 5,270,170) and Barbas, III (U.S. 6,242,568). Claims 1, 5, 9, and their dependents are discussed above. Claims 17 and 22 recite bacteriophage with at least 10 copies of ligand on the surface of each bacteriophage. Claims 58 and 62 recite at least 100 copies of the ligand on the surface of each bacteriophage. Claims 59 and 63 recite at least 400 copies of the ligand.

The teachings of Shatz are discussed above. Barbas does not teach virus expressing at least 10 copies of a polypeptide ligand. Moreover, Barbas could not inherently disclose this limitation because the art had not found it possible to express that many protein molecules on a filamentous phage surface. See the enclosed review article entitled "Vectors for Phage Display" by Armstrong et al., in Phage Display of Peptides and Proteins 1996, Academic Press, which teaches that only gene III fusions are appropriate for expressing protein because gene VIII does not tolerate more than 5-6 amino acid long inserts. Page 35, lines 5-8. Moreover, gene III fusions typically provide monovalent display (0-1 or 0-5 copies per phage particle: pages 37 and 50. Barbas does not teach or suggest the expression *of at least 10 protein molecules* on the viral surface. Therefore, Barbas does not teach or suggest methods which require the expression of at least 10 copies of a polypeptide ligand on their surface, *i.e.*, claims 17, 22, and 58-72. Barbas also does not remedy the deficiency of Shatz in teaching the methods of claims 1, 5, and 9. Thus, the combination of Shatz and Barbas fails to teach all elements of the claims.

CONCLUSION

It is believed that a fee for three (3) extra dependent claims is required for this submission. If any additional fees are required or if an overpayment is made, the Commissioner is authorized to debit or credit our Deposit Account No. 19-0733, accordingly.

All rejections having been addressed, applicant respectfully submits that the instant application is in condition for allowance, and respectfully solicits prompt notification of the same.

Respectfully submitted,

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